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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/656,811	06/03/96	BARTSCH	50365/JPW/JM

HM21/0805

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EXAMINER	
BAKALYAR,H	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/05/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/656,811	Applicant(s) Bartsch
	Examiner Heather Bakalyar	Group Art Unit 1645

☒ Responsive to communication(s) filed on *May 14, 1998* .

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-27* is/are pending in the application.

Of the above, claim(s) *2, 7-14, 17, and 23-27* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 3-6, 15, 16, and 18-22* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The Art Unit location of U.S. Patent Application 08/656,811 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Technology Center 1600, Group 1640, Art Unit 1645.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The amendment and Declaration under 37 CFR 1.132 filed 5/14/98 (Paper No. 11) is acknowledged and has been entered.

Claim(s) 1, 4, 5, 6, 15-16, 19-20, 22 have been amended.
Claim(s) 1-27 are pending and subject to restriction/election requirement.

4. The Declaration under 37 CFR 1.132 filed 5/14/98 is sufficient to overcome the rejection of claims 1, 3-6, 15-16, 18-22 based upon 35 U.S.C. 102 (Bartsch et al).

Election/Restriction

5. Claim(s) 1, 3-6, 15-16, 18-22 are examined. Non-elected claim(s) 2, 7-14, 17, 23-27 are withdrawn from consideration. Additionally, as per Paper No(s). 8-10, an election of species was imposed regarding species of claims 4 and 19. Applicant elected "small molecule". The amendment filed 5/14/98 (Paper No. 11) deletes "small molecule" from claims 4, and 19 without identification of another species for prosecution. In response, the examiner has chosen to examine "peptide" in claims 4 and 19.

Claim Objections

6. Claim 15 and dependent claims are objected to because of the following informalities: claim 15 recites "inhbiting", a mis-spelling of "inhibiting". Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

7. The rejection of claims 15-16, 18-22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are maintained for the reasons set forth in Paper No(s). 10.

a. Claim 15 recites "defect". See rejection in Paper No(s). 10, which Applicant has not traversed.

b. Claims 1, 3-6, 15-16, 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation(s) of "improve" in throughout the claims is/are vague and indefinite. It is not clear by what criteria this improvement is judged (e.g. amount of training required to create long term memory; duration of a long-term memory; clarity of a long-term memory; or other).

8. The rejection of claim(s) 1, 3-6, 15-16, 18-22 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, is maintained for the reasons set forth in Paper No(s). 10 filed 11/10/97.

Applicant's arguments filed 5/14/98 (Paper No. 11) have been fully considered but are not persuasive. Applicant argues/alleges on pages 13-15 that (a) the specification allegedly comprises working examples though Applicant does not point to such Examples (b) not all actual embodiments need be disclosed (c) the factors which must be considered under MPEP 2164.01

are satisfied (d) complex experimentation is not necessarily "undue" experimentation (e) disclosed experiments that "show that cAMP-responsive gene expression correlates to memory function" (page 14 of Paper No(s). 11) enable the claims (f) Applicant cites in re Brana in the context of human trials and MPEP 2107.02 for "reasonable correlation" (in vitro- in vivo; activity-asserted utility; human trials) to support utility of the claimed invention.

In response: (a) The claims are drawn to methods of improving long term memory and in subjects with either a low cAMP responsive gene expression (independent claim 1) or a memory defect (independent claim 15). As set forth in the previous Office action, the skilled artisan distinguishes long term potentiation in Aplysia from complex memory processes in primates, further, long term potentiation as a model for memory process in Aplysia itself has been critiqued. Therefore, the art teaches that long term facilitation is not equivalent to long term memory. Other aspects of the claims, such as improvement of long term memory in particular subject populations (defined by low cAMP responsive gene expression, general or specific memory defect) are not addressed in the working examples.

Further, (b-e) though it is agreed that all actual embodiments need not be disclosed and complex experimentation is not necessarily "undue" experimentation, the factors which must be considered under MPEP 2164.01 (see also in re Wands) in regard to the instant invention is not satisfied. For example, the working example(s) are not drawn to the claimed subject matter (also see (e) above, the working examples may show that particular cAMP-responsive gene expression correlates to long term facilitation, however, this is not what is claimed), the nature of the invention is highly complex, the breadth of the claims is extensive and encompasses specific

human conditions of different etiologies, and the art points to unpredictablitity (e.g. see Paper No(s). 10). In contrast to Applicant's assertion on page 14 that the quantity of experimentation would not be great because allegedly the exchange of particulars of the examples for other embodiments id allegedly "routine", for the reason set forth above and in Paper No(s). 10, one of skill would have reason to doubt the correlation between disclosed examples and the claimed invention, and therefore the experimentation would require creative input and success would be highly unpredictable.

(f) Applicant's citation of in re Brana and MPEP 2107.02 are not on point because the method claims are rejected for lack of enablement, not utility. However, the Examiner notes that human trials are not called for, and importantly the correlation between what is disclosed and what is claimed is not unpredictable for the reasons above and in Paper No(s). 10.

Claim Rejections - 35 U.S.C. § 102

9. The rejection of claim(s) 1, 3-5, 15, 18-21 under 35 U.S.C. 102 (a or b) as being anticipated by Yin is maintained, for the reasons set forth in Paper No(s). 10 filed 11/10/97.

Applicant's arguments filed 5/14/98 (Paper No. 11) have been fully considered but are not persuasive. Applicant argues on page 18 that: (a) overexpression of dCREB-2a reduces the number of training trials needed to establish long term memory (b) that the Examiner asserts without support that dCREB-2a interferes with CRE binding (c) that Yin does not teach a method wherein the subject population which has decreased cAMP responsive gene expression due to binding of CREBP2 to a protein or DNA required for this binding.

In response: (a) Reduction training needed to establish long term memory reads upon improved long term memory. (b) CREBP (CRE binding protein) by definition binds CRE. Claims 1 and 15 use "capable of" language, dCREB-2a is capable of binding CRE. Therefore, the single method step of the claim is fulfilled. Addtionally, the final outcome of the claim, improved memory, is disclosed. Though the authors admit the exact mechanism of action is not known, one of skill in the art would expect that the modulation of cAMP gene expression is an inherent property of the method, because of CRE's role in this expression, and as above, Yin et al anticipate all the method steps of the instant claims. (C) The claims no longer recite this limitation.

Upon reconsideration, the rejection of claims 6, 16, 22 is withdrawn.

Response to Arguments

See above.

Status of Claims

10. No claims are allowed.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

12. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current official FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather Bakalyar, whose telephone number is (703) 305-7143. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, Ph.D., can be reached at (703) 308-4310.

Heather A. Bakalyar, Ph.D.
Patent Examiner
8/2/98

PAULA K. HUTZELL
SUPERVISORY PATENT EXAMINER